

5378 '99 NOV 23 P1 55

November 12, 1999

Dockets Management Branch (HFA-305)
Room 1061
U.S. Food & Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Dear Sir or Madam:

Re: Docket No. 99D-4201 (Dioxin in Mined Clays Used in Animal Feeds)

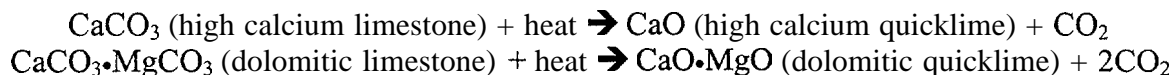
On October 15, 1999, FDA announced the availability of a guidance document on "Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients (October 6, 1999)" [64 Fed. Reg. 55948]. The guidance is being implemented immediately without prior public comment. The National Lime Association (NLA) is commenting because the guidance includes "lime" in the list of materials found to contain dioxin.

NLA respectfully requests that the FDA immediately rescind the guidance because it mistakenly includes "lime" based on a single, mislabeled sample. This error, if not corrected immediately, will significantly harm lime manufacturers, as customers will wrongly be concerned that lime contains dioxin.

The mislabeled sample consisted of limestone (i.e., calcium carbonate) sold by Franklin Industrial Materials (FIM). Calcium carbonate is an entirely different substance than lime (i.e., calcium oxide or calcium hydroxide). FIM does not sell lime.

Lime and Limestone Are Different Materials

NLA is the trade association for manufacturers of high calcium quicklime, dolomitic quicklime, and hydrated lime, collectively referred to as "lime." Lime is created by converting limestone into quicklime -- an entirely different chemical than limestone:



99D-4201

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Unlike limestone, lime is not a naturally-occurring mineral. Rather, an energy-intensive manufacturing process is needed to create quicklime. (The second form of lime, hydrated lime, is created by chemically reacting quicklime with water.) High purity limestone feedstocks are used in order to produce lime that can meet the demanding specifications of lime's many applications, such as the *Food Chemicals CODEX* specifications.

Both limestone (calcium carbonate) and lime (calcium oxide/hydroxide) are sometimes referred to as "aglime." Both are used in manufacturing animal feeds. Nevertheless, as noted above, they are two different materials.

FDA's Guidance

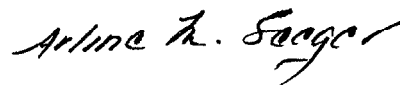
The FDA guidance lists "lime" as a material found to contain dioxins. This is based on FDA Sample Number 37950, described as "lime, used in soy meal manufacturing," supplied by FIM to the Bunge Corporation. According to FIM, however, the sample is limestone, not lime. As noted above, FIM does not sell lime.

The finding that the sample of limestone contained dioxin is highly suspect. The levels found in limestone (0.43 ppt TEQ) were the lowest positive results reported for any of the samples in the program, and appear to be near or below the detection limits in the study. (The sampling summary lists the following "apparent limits of detection": 4.0 ppt for octas, 0.6 ppt for pentas, and 0.2 ppt for tetras.) The summary does not present the basis of the 0.43 ppt TEQ result.

Even if the dioxin finding is a real value, there is an explanation for this anomalous result: the sampled limestone was reportedly contaminated with ball clay. It is our understanding that FDA has already discussed the study's sampling procedures with the limestone manufacturer, FIM. FIM has discovered that the bulk tank its customer used to store the limestone was used less than a week before to store ball clay.

To avoid unnecessarily frightening or misleading the public, FDA should rescind or modify the flawed guidance immediately, to delete any suggestion that "lime" has been found to contain dioxin. There is no reason to think that a corrected guidance document cannot be reissued shortly after the close of a public comment period. The result will be a more accurate evaluation of potential threats to public health from mined clay materials.

Sincerely,



Arline M. Seeger
Executive Director

NATIONAL LIME ASSOCIATION

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